

§ 170.45

for the particular use will require a food additive regulation. This notification will be placed on public display at the Dockets Management Branch as part of the file of uses of substances exempted from regulation as food additives. The Food and Drug Administration recognizes that manufacturers other than those that actually made a request for exemption may also be using exempted substances in food-contact articles under conditions of use (e.g., use levels, temperature, type of food contacted, etc.) that are similar to those for which the exemption was issued. Because only requestors will be notified as part of the revocation process described in this section, the Food and Drug Administration plans to notify other manufacturers by means of a notice published in the FEDERAL REGISTER of its decision to revoke an exemption issued for a specific use of a substance in a food contact article.

(h) Guidance documents to assist requestors in the preparation of submissions seeking exemptions from the food additive regulations are available from the Food and Drug Administration's Office of Premarket Approval (HFS-200), 5100 Paint Branch Pkwy., College Park, MD 20740. Interested persons are encouraged to obtain specific guidance from the Food and Drug Administration on the appropriate protocols to be used for obtaining migration data, on the validation of the analytical methods used to quantify migration levels, on the procedures used to relate migration data to dietary exposures, and on any other issue not specifically covered in the Food and Drug Administration's guidance documents.

[60 FR 36595, July 17, 1995, as amended at 62 FR 40599, July 29, 1997; 65 FR 56479, Sept. 19, 2000]

Subpart C—Specific Administrative Rulings and Decisions

§ 170.45 Fluorine-containing compounds.

The Commissioner of Food and Drugs has concluded that it is in the interest of the public health to limit the addition of fluorine compounds to foods (a) to that resulting from the fluoridation of public water supplies as stated in § 250.203 of this chapter, (b) to that re-

21 CFR Ch. I (4–1–02 Edition)

sulting from the fluoridation of bottled water within the limitation established in § 103.35(d) of this chapter, and (c) to that authorized by regulations (40 CFR part 180) under section 408 of the Act.

§ 170.50 Glycine (aminoacetic acid) in food for human consumption.

(a) Heretofore, the Food and Drug Administration has expressed the opinion in trade correspondence that glycine is generally recognized as safe for certain technical effects in human food when used in accordance with good manufacturing practice; however:

(1) Reports in scientific literature indicate that adverse effects were found in cases where high levels of glycine were administered in diets of experimental animals.

(2) Current usage information indicates that the daily dietary intake of glycine by humans may be substantially increasing due to changing use patterns in food technology.

Therefore, the Food and Drug Administration no longer regards glycine and its salts as generally recognized as safe for use in human food and all outstanding letters expressing sanction for such use are rescinded.

(b) The Commissioner of Food and Drugs concludes that by May 8, 1971, manufacturers:

(1) Shall reformulate food products for human use to eliminate added glycine and its salts; or

(2) Shall bring such products into compliance with an authorizing food additive regulation. A food additive petition supported by toxicity data is required to show that any proposed level of glycine or its salts added to foods for human consumption will be safe.

(c) The status of glycine as generally recognized as safe for use in animal feed, as prescribed in § 582.5049 of this chapter, remains unchanged because the additive is considered an essential nutrient in certain animal feeds and is safe for such use under conditions of good feeding practice.

§ 170.60 Nitrites and/or nitrates in curing premixes.

(a) Nitrites and/or nitrates are food additives when combined in curing premixes with spices and/or other flavoring or seasoning ingredients that

Food and Drug Administration, HHS

§ 171.1

contain or constitute a source of secondary or tertiary amines, including but not limited to essential oils, disodium inosinate, disodium guanylate, hydrolysates of animal or plant origin (such as hydrolyzed vegetable protein), oleoresins of spices, soy products, and spice extractives. Such food additives may be used only after the establishment of an authorizing food additive regulation. A food additive petition submitted pursuant to §§171.1 and 171.100 of this chapter, supported by data demonstrating that nitrosamines are not formed in curing premixes containing such food additives, is required to establish safety.

(b) Nitrites and/or nitrates, when packaged separately from flavoring and seasoning in curing premixes, may continue to be used under prior sanctions in the commercial curing of meat and meat products and poultry products and in accordance with the provisions of §§172.170 and 172.175 of this chapter that apply to meat curing preparations for the home curing of meat and meat products, including poultry and wild game. To assure safe use of such ingredients the labeling of the premixes shall bear instructions to the user that such separately packaged ingredients are not to be combined until just prior to use. Encapsulating or coating some or all of the ingredients does not constitute separate packaging.

PART 171—FOOD ADDITIVE PETITIONS

Subpart A—General Provisions

Sec.

171.1 Petitions.

171.6 Amendment of petition.

171.7 Withdrawal of petition without prejudice.

171.8 Threshold of regulation for substances used in food-contact articles.

Subpart B—Administrative Actions on Applications

171.100 Regulation based on petition.

171.102 Effective date of regulation.

171.110 Procedure for objections and hearings.

171.130 Procedure for amending and repealing tolerances or exemptions from tolerances.

AUTHORITY: 21 U.S.C. 321, 342, 348, 371.

SOURCE: 42 FR 14489, Mar. 15, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 171.1 Petitions.

(a) Petitions to be filed with the Commissioner under the provisions of section 409(b) of the Federal Food, Drug, and Cosmetic Act (the act) shall be submitted in triplicate (quadruplicate, if intended uses include use in meat, meat food product, or poultry product). If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The petition shall state petitioner's post office address to which published notices or orders issued or objections filed pursuant to section 409 of the Act may be sent.

(b) Pertinent information may be incorporated in, and will be considered as part of, a petition on the basis of specific reference to such information submitted to and retained in the files of the Food and Drug Administration. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized in a written statement signed by the person who submitted it. Any reference to published information offered in support of a food additive petition should be accompanied by reprints or photostatic copies of such references.

(c) Petitions shall include the following data and be submitted in the following form:

(Date)
Name of petitioner _____
Post-office address _____
Date _____
Name of food additive and proposed use _____

Petitions Control Branch
Food and Drug Administration
Department of Health and Human Services
Washington, DC 20204.

DEAR SIRs:

The undersigned, _____ submits this petition pursuant to section 409(b)(1) of the Federal Food, Drug, and Cosmetic Act with respect to _____

(Name of the food additive and proposed use)